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10/008,264	12/03/2001	Laurie H. Glimcher	HUI-040CP	2529

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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/008,264	GLIMCHER ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. *Claims* 1 – 49 *are pending.*

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

3. For examination purposes the following is noted:

Claim 1 recites a nucleic acid molecule comprising a sequence encoding a T-bet protein. Dependent claim 2 recites the nucleic acid molecule of claim 1 encoding a human T-bet (SEQ ID NO:1), while dependent claim 3 recites the nucleic acid molecule of claim 2 encoding a murine T-bet (SEQ ID NO:3). It appears that claim 3 was intended to depend on claim 1 rather than claim 2, and is being treated as such in the instant Office Action.

Likewise, claims 14 – 20 recite "the protein of claim 12," whereas claim 12 is drawn to a method of producing the protein. It is assumed for examination purposes that claims 14 – 20 were intended depend on claim 13 rather than claim 12.

Applicant is required to clarify or correct claim dependency in response to this Office Action.

4. Applicant is invited to proofread the claims and correct apparent spelling errors, such as those in claims 39 and 43(b).

Restriction Requirement

4. The following is noted:

The claims are drawn to nucleic acids, proteins, antibodies and methods relating to either human or mouse T-bet proteins. These proteins vary in composition and possess different structures, sequences, and properties, which require non-coextensive searches in the scientific literature.

Consequently, the restriction has been set forth for claims directed to human and mouse molecules as different groups, irrespective of the format of the claims.

5. Claims 27, 29 – 31, and dependent claims thereof are drawn to the following patentably distinct Inventions, wherein the indicator or indicator composition comprises either a combination of T-bet protein with a DNA molecule to which the T-bet protein binds, or a cell comprising a T-bet protein and a reporter gene. These products are distinct because their structures, physicochemical properties and mode of action are different. Furthermore, the examination of these products would require different searches in the scientific literature.

Consequently, the restriction has been set forth for claims directed to these two types of indicator compositions as different groups, irrespective of the format of the claims.

6. Claim 28 contains a recitation of modulation of T-bet activity, whereas dependent claims 33 and 34 contain recitations of either enhancing and inhibiting T-bet activity, respectively. These methods are mutually exclusive in that they reach opposing endpoints, and in that they employ structurally distinct products to accomplish these mutually exclusive endpoints.

Consequently, the restriction has been set forth for claims directed to methods wherein T-bet activity is enhanced or inhibited as different groups, irrespective of the format of the claims.

7. Claims 28 and 29 contain recitations of methods which include the step of "contacting," while dependent claims 37 and 38 contain recitation of "contacting" occurring either in vivo or in vitro. These methods are distinct in that they differ in method steps. Therefore, the restriction has been set forth for claims directed to methods involving contacting in vivo or in vitro as different groups, irrespective of the format of the claims.

8. Claim 28 contains recitation of an "agent," while dependent claims 39 and 40 contain recitation of agents which include a T-bet nucleic acid molecule, a T-bet peptide, a small molecule T-bet agonist or antagonist, an intracellular antibody, an antisense nucleic acid molecule, or a dominant negative T-bet molecule. These agents are distinct because their structures, physicochemical properties and mode of action are different. Furthermore, the examination of these agents would require different searches in the scientific literature.

Consequently, the restriction has been set forth for claims directed to these types of agents as different groups, irrespective of the format of the claims.

9. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Groups 1 – 40 are directed to human proteins or nucleic acids, and Groups 41 – 80 are directed to mouse proteins or nucleic acids, respectively.

Group 1. Claims 1, 2, 4, 6, and 8 – 12, drawn to an isolated nucleic acid encoding human T-bet protein, as well as vectors, host cells, and methods of producing

the protein, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

Group 2. Claims 1, 3, 5, 7, and 8 – 12, drawn to an isolated nucleic acid encoding mouse T-bet protein, as well as vectors, host cells, and methods of producing the protein, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

The following Groups of claims are directed to either human (Groups 3 – 41) or mouse (Groups 42 – 80) proteins or nucleic acids.

Groups 3 and 42. Claims 13, 14, 16, 18, and 20, drawn to and isolated T-bet protein, classified in Class 530, subclass 350.

Groups 4 and 43. Claim 21, drawn to a fusion protein of T-bet, classified in Class 530, subclass 387.3.

Groups 5 and 44. Claims 22 – 25, drawn to antibodies to T-bet protein, classified in Class 530, subclass 387.1.

Groups 6 and 45. Claim 26, drawn to a nonhuman transgenic animal carrying a transgene encoding a T-bet protein, classified in Class 800, subclass 14.

Groups 7 and 46. Claim 27, drawn to method for detecting the presence of T-bet in a biological sample, wherein the indicator comprises a T-bet protein and a DNA molecule to which it binds, classified in Class 435, subclass 6.

Groups 8 and 47. Claim 27, drawn to method for detecting the presence of T-bet in a biological sample, wherein the indicator is a cell comprising a T-bet protein and reporter gene, classified in Class 435, subclass 70.1.

Groups 9 and 48. Claims 28, 33, 35 – 37, and 39 – 42, drawn to a method for enhancing T-bet activity, wherein the step of contacting occurs in vivo, and wherein the agent is a T-bet nucleic acid molecule, classified in Class 514, subclass 44.

Groups 10 and 49. Claims 28, 33, 35 – 37, and 39 – 42, drawn to a method for enhancing T-bet activity, wherein the step of contacting occurs in vivo, and wherein the agent is a T-bet peptide, classified in Class 514, subclass 21.

Groups 11 and 50. Claims 28, 33, 35 – 37, and 39 – 42, drawn to a method for enhancing T-bet activity, wherein the step of contacting occurs in vivo, and wherein the agent is a small molecule T-bet agonist, classified in Class 514, subclass 21.

Groups 12 and 51. Claims 28, 33, 35 – 37, and 39 – 42, drawn to a method for enhancing T-bet activity, wherein the step of contacting occurs in vivo, and wherein the agent is a small molecule T-bet antagonist, classified in Class 514, subclass 21.

Groups 13 and 52. Claims 28, 33, 35 – 37, and 39 – 42, drawn to a method for enhancing T-bet activity, wherein the step of contacting occurs in vivo, and wherein the agent is an intracellular antibody, classified in Class 424, subclass 133.1.

Groups 14 and 53. Claims 28, 33, 35 – 37, and 39 – 42, drawn to a method for enhancing T-bet activity, wherein the step of contacting occurs in vivo, and wherein the agent is an antisense nucleic acid molecule, classified in Class 514, subclass 44.

Groups 15 and 54. Claims 28, 33, 35 – 37, and 39 – 42, drawn to a method for enhancing T-bet activity, wherein the step of contacting occurs in vivo, and wherein the agent is a dominant negative T-bet molecule, classified in Class 514, subclass 21.

Groups 16 and 55. Claims 28, 33, 35 – 36, and 38 – 42, drawn to a method for enhancing T-bet activity, wherein the step of contacting occurs in vitro, and wherein the agent is a T-bet nucleic acid molecule, classified in Class 435, subclass 6.

Groups 17 and 56. Claims 28, 33, 35 – 36, and 38 – 42, drawn to a method for enhancing T-bet activity, wherein the step of contacting occurs in vitro, and wherein the agent is a T-bet peptide, classified in Class 514, subclass 21.

Groups 18 and 57. Claims 28, 33, 35 – 36, and 38 – 42, drawn to a method for enhancing T-bet activity, wherein the step of contacting occurs in vitro, and wherein the agent is a small molecule T-bet agonist, classified in Class 514, subclass 21.

Groups 19 and 58. Claims 28, 33, 35 – 36, and 38 – 42, drawn to a method for enhancing T-bet activity, wherein the step of contacting occurs in vitro, and wherein the agent is a small molecule T-bet antagonist, classified in Class 435, subclass 6.

Groups 20 and 59. Claims 28, 33, 35 – 36, and 38 – 42, drawn to a method for enhancing T-bet activity, wherein the step of contacting occurs in vitro, and wherein the agent is an intracellular antibody, classified in Class 424, subclass 133.1.

Groups 21 and 60. Claims 28, 33, 35 – 36, and 38 – 42, drawn to a method for enhancing T-bet activity, wherein the step of contacting occurs in vitro, and wherein the agent is an antisense nucleic acid molecule, classified in Class 435, subclass 6.

Groups 22 and 61. Claims 28, 33, 35 – 36, and 38 – 42, drawn to a method for enhancing T-bet activity, wherein the step of contacting occurs in vitro, and wherein the agent is a dominant negative T-bet molecule, classified in Class 514, subclass 21.

Groups 23 and 62. Claims 28, 34, 35 – 37, and 39 – 42, drawn to a method for inhibiting T-bet activity, wherein the step of contacting occurs in vivo, and wherein the agent is a T-bet nucleic acid molecule, classified in Class 514, subclass 44.

Groups 24 and 63. Claims 28, 34, 35 – 37, and 39 – 42, drawn to a method for inhibiting T-bet activity, wherein the step of contacting occurs in vivo, and wherein the agent is a T-bet peptide, classified in Class 514, subclass 21.

Groups 25 and 64. Claims 28, 34, 35 – 37, and 39 – 42, drawn to a method for inhibiting T-bet activity, wherein the step of contacting occurs in vivo, and wherein the agent is a small molecule T-bet agonist, classified in Class 514, subclass 21.

Groups 26 and 65. Claims 28, 34, 35 – 37, and 39 – 42, drawn to a method for inhibiting T-bet activity, wherein the step of contacting occurs in vivo, and wherein the agent is a small molecule T-bet antagonist, classified in Class 514, subclass 21.

Groups 27 and 66. Claims 28, 34, 35 – 37, and 39 – 42, drawn to a method for inhibiting T-bet activity, wherein the step of contacting occurs in vivo, and wherein the agent is an intracellular antibody, classified in Class 424, subclass 133.1.

Groups 28 and 67. Claims 28, 34, 35 – 37, and 39 – 42, drawn to a method for inhibiting T-bet activity, wherein the step of contacting occurs in vivo, and wherein the agent is an antisense nucleic acid molecule, classified in Class 514, subclass 44.

Groups 29 and 68. Claims 28, 34, 35 – 37, and 39 – 42, drawn to a method for inhibiting T-bet activity, wherein the step of contacting occurs in vivo, and wherein the agent is a dominant negative T-bet molecule, classified in Class 514, subclass 21.

Groups 30 and 69. Claims 28, 34, 35, 36, and 38 – 42, drawn to a method for inhibiting T-bet activity, wherein the step of contacting occurs in vitro, and wherein the agent is a T-bet nucleic acid molecule, classified in Class 435, subclass 6.

Groups 31 and 70. Claims 28, 34, 35, 36, and 38 – 42, drawn to a method for inhibiting T-bet activity, wherein the step of contacting occurs in vitro, and wherein the agent is a T-bet peptide, classified in Class 514, subclass 21.

Groups 32 and 71. Claims 28, 34, 35, 36, and 38 – 42, drawn to a method for inhibiting T-bet activity, wherein the step of contacting occurs in vitro, and wherein the agent is a small molecule T-bet agonist, classified in Class 514, subclass 21.

Groups 33 and 72. Claims 28, 34, 35, 36, and 38 – 42, drawn to a method for inhibiting T-bet activity, wherein the step of contacting occurs in vitro, and wherein the agent is a small molecule T-bet antagonist, classified in Class 514, subclass 21.

Groups 34 and 73. Claims 28, 34, 35, 36, and 38 – 42, drawn to a method for inhibiting T-bet activity, wherein the step of contacting occurs in vitro, and wherein the agent is an intracellular antibody, classified in Class 424, subclass 133.1.

Groups 35 and 74. Claims 28, 34, 35, 36, and 38 – 42, drawn to a method for inhibiting T-bet activity, wherein the step of contacting occurs in vitro, and wherein the agent is an antisense nucleic acid molecule, classified in Class 435, subclass 6.

Groups 36 and 75. Claims 28, 34, 35, 36, and 38 – 42, drawn to a method for inhibiting T-bet activity, wherein the step of contacting occurs in vitro, and wherein the agent is a dominant negative T-bet molecule, classified in Class 514, subclass 21.

Groups 37 and 76. Claims 29, 30, 32, 33, and 35 – 42, drawn to a method for identifying compounds that enhance the activity of T-bet protein, wherein the indicator

composition comprises a T-bet protein and a DNA molecule to which it binds, classified in Class 435, subclass 6.

Groups 38 and 77. Claims 29, 31 – 33, and 35 – 42, drawn to a method for identifying compounds that enhance the activity of T-bet protein, wherein the indicator composition is a cell comprising a T-bet protein and reporter gene, classified in Class 435, subclass 70.1.

Groups 39 and 78. Claims 29, 30, 32 and 34 – 42, drawn to a method for identifying compounds that inhibit the activity of T-bet protein, wherein the indicator composition comprises a T-bet protein and a DNA molecule to which it binds, classified in Class 435, subclass 6.

Groups 40 and 79. Claims 29, 31, 32 and 34 – 42, drawn to a method for identifying compounds that inhibit the activity of T-bet protein, wherein the indicator composition is a cell comprising a T-bet protein and reporter gene, classified in Class 435, subclass 70.1.

Groups 41 and 80. Claims 43 – 49, drawn to a method of diagnosing a subject based on a change in expression of T-bet protein, classified in Class 435, subclass 7.1.

6. Groups I – X are different products. Nucleic acids, polypeptides, fusion proteins, antibodies to the polypeptides, and transgenic animals differ with respect to their structures and physicochemical properties and require non-coextensive searches, therefore each product is patentably distinct.

Groups XI – XXXXV are different methods. A method of detecting, a method of modulating, a method of identifying and a method of diagnosing differ with respect to

ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct.

Certain Inventions from Groups III – X and certain Inventions from Groups XI – XXXXV are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Groups III – X can be used for producing antibodies, in addition to the methods of detecting, modulating, identifying and diagnosing recited.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

9. This application contains claims directed to the following patentably distinct species of the claimed Inventions XIII – XXXXIV, wherein the activity of T-bet is:

(A) IFN-γ production, or

(B) transcription of IgG2a.

These species are distinct because the methods differ with respect to ingredients, method steps and endpoints.

9. This application contains claims directed to the following patentably distinct species of the claimed Inventions XIII – XXXXIV, wherein the cell is:

(A) a T cell,

(B) a B cell, or

(C) a macrophage.

These species are distinct because their structures, physicochemical properties and mode of action are different. Furthermore, the examination of these species would require different searches in the scientific literature.

12. This application contains claims directed to the following patentably distinct species of the claimed Invention XXXXV, wherein the disorder is:

(A) lupus

(B) Inflammatory Bowel Disease,

(C) Crohn's disease,

(D) ulcerative colitis, or

(E) asthma.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

13. It is noted that claim 28 recites a method for T-bet modulating activity in a cell, presumably with the intent of treating a disorder in a patient. In the event that specific disorders are introduced into the claims during prosecution, additional restriction or species election will be required.

13. Applicant is required under 35 USC 121 to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable. Currently, claim 43, for example, is generic.

14. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise*

include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Patent Examiner
Art Unit 1644

August 9, 2004

PHILLIP GAMBEL, PH.D
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8/16/04